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| 23377 7590 10/02/2008 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891 | | | | |
| EXAMINER PITRAK, JENNIFER S | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1635 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,981

Applicant(s)

CRANENBURGH, ROCKY MARC

Examiner

JENNIFER PITRAK

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10, 11, 13-41, 44, 45 and 72 is/are pending in the application.
- 4a) Of the above claim(s) 18, 19, 21-26, 30-35, 38-40, 44, 45 and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10, 11, 27-29, 36, 37, and 41 is/are rejected.
- 7) ☒ Claim(s) 13-17 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Remarks

Applicant's amendments and arguments filed 06/17/2008 have been entered and considered. The rejections set forth herein are either newly presented or maintained. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 10, 11, 13-17, 20, 27-29, 36, 37, and 41 are under examination.

Sequence Compliance

Applicants filed a sequence listing and amended the specification to comply with 37 C.F.R. §§ 1.821-1.825.

Claim Rejections - 35 USC § 112 - Withdrawn

The amendments to claims 36 and 37 have obviated the rejection of the claims under 35 U.S.C. 112.

Claim Rejections - 35 USC § 112 – New

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is to a pharmaceutical composition, which inherently has the intended use of treating a subject, namely a human. The

removal of the term "pharmaceutical" from the claim would eliminate the inherent use that is addressed in this rejection.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112, first paragraph, the following factors enumerated *In re Wands*, 8 USPQ2d 1400, at 1404 (CAFC 1988) are considered: (1) the breadth of the claims, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the quantity of experimentation necessary. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

The claim is to a pharmaceutical composition comprising a transformed host cell according to claim 1. Claim 1 encompasses transformed host cells that include a very broad range of cells from bacteria to human cells (specification p.17, lines 10-11). The claim encompasses such host cells that do or do not contain a gene of interest. The specification describes that the gene of interest that may be incorporated into the vector of claim 1 may be any gene, including a gene that will be transcribed only, transcribed and translated in the host cell, or transcribed and translated in the recipient organism in which therapy is desired (pp. 18-19). The specification describes that there are any number of routes of administration of the transformed host cells including by intradermal or subcutaneous injection, oral, rectal, mucosal intravenous, intraperitoneal, enteral, and parenteral administration, as well as administration by the use of implantable permeable containers in which the host cells are contained (p.19, lines 15-26). The specification does not provide any working examples that demonstrate a therapeutic effect of administering transformed host cells according to the invention. The prior art provides no

support for a therapeutic use of a transformed host cell comprising an inhibitory chromosomal gene operably linked to a regulatory sequence and a plasmid comprising an origin of replication encoding an antisense sequence which binds to the regulatory sequence. Thus, the claim is highly unpredictable with regard to a therapeutic result of using the claimed composition. One of skill in the art would not be apprised of what genes or sequences, if any, could be expressed from the transformed host cell of claim 1 and coordinately result in a therapeutic effect upon administration of the host cell to a recipient organism. Thus, claim 41 is not enabled.

Claim Rejections - 35 USC § 101 - New

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 10, 11, 27-29, 36, and 37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The term “host cell” as defined by the specification at page 17, lines 10-18, includes include cells that are present or are intended to be present in a human being when used for human therapy, which is non-statutory subject matter. As such, the recitation of the limitation “non-human” or “isolated” would be remedial. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 103

Applicants’ arguments traversing the rejection of claims 1-3, 10, 11, 13-17, 20, 27-29, 36, 37, and 41 under 35 U.S.C. § 103(a) are persuasive. Therefore, the rejection of these claims under 35 U.S.C. § 103(a) are withdrawn.

Allowable Subject Matter

Claims 13-17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak, PhD
Examiner
Art Unit 1635

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635